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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/550,038	09/21/2005		Michael Barry Gravestock	100869-1P US	8079
44992	7590	04/13/2006	EXAMINER		INER
		&D BOSTON	CHU, YONG LIANG		
35 GATEHO WALTHAM		-		ART UNIT	PAPER NUMBER
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				DATE MAIL ED: 04/13/200	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Office Action Comments	10/550,038	GRAVESTOCK ET AL.					
Office Action Summary	Examiner	Art Unit					
	Yong Chu	1626					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	Lely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status		·					
1) Responsive to communication(s) filed on 05 Ja	nuary 2006	•					
	action is non-final.						
3) Since this application is in condition for allowan		secution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-6,8 and 11-13</u> is/are pending in the	application.						
· · · · · · · · · · · · · · · · · · ·	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)☐ Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) 1-6,8 and 11-13 are subject to restricti	ion and/or election requirement.	•					
Application Papers							
<u> </u>	•						
9) The specification is objected to by the Examiner							
10) The drawing(s) filed on is/are: a) acce							
Applicant may not request that any objection to the c	<del>- · · ·</del>	• •					
Replacement drawing sheet(s) including the correcti		• • • •					
11) The oath or declaration is objected to by the Exa	aminer. Note the attached Office	Action of form P10-152.					
Priority under 35 U.S.C. § 119	•						
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).					
1. Certified copies of the priority documents	have been received.						
2. Certified copies of the priority documents		on No.					
3. Copies of the certified copies of the priori	* *						
application from the International Bureau	•						
* See the attached detailed Office action for a list of	of the certified copies not receive	d.					
	·						
Attachmont(c)							
Attachment(s)  Notice of References Cited (PTO-892)	4) Interview Summary	(PTO.413)					
2) Notice of References Cited (P10-692)  Notice of Draftsperson's Patent Drawing Review (PT0-948)	Paper No(s)/Mail Da						
Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal Page 6) Other:	atent Application (PTO-152)					

### **DETAILED ACTION**

Claims 2-6, 8, and 11 are amended and claims 7, and 9-10 are cancelled by amendment filed on 23 September 2005. Therefore, claims 1-6, 8, 11-13 are currently pending in the instant application.

#### **Priority**

This application is a 371 of PCT/GB04/01132, filed on 16 March 2004.

Acknowledgement is made of Applicant's claim for UK Patent Application 0306357.5 under 35 U.S.C. § 119(a-d), filed on 20 March 2004.

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

#### Lack of Unity Requirement

Claims 1-31 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

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PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-6, and 11 are drawn to a compound of formula (I)

or a pharmaceutically acceptable salt, or an in-vivo-hydrolysable ester thereof.

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**Group II**: Claim 8 is drawn to a method for producing an antibacterial effect in a warm-blooded animal, comprising administering to said animal an effective amount of a compound of claim 1

**Group III**: Claims 12 are drawn to a process for the preparation of a compound of formula (I) as claimed in claim 1 or a pharmaceutically acceptable salts or in-vivo hydrolysable esters thereof, which process comprises one of processes (a) to (g).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-III** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-III** is

technical feature is not a special technical feature, because it fails to define a

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contribution over the compound

al. WO 2001-GB1815. Therefore, claims 1-6, 8, 11-13 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to <u>a</u> product, <u>a</u> process for the manufacture of said product, or <u>a</u> method of use.

Furthermore, with respect to **Groups I-VI**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

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Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less that one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

## Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yong Chu Ph D

Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER

Joseph M<sup>⊆</sup>Kane

Supervisory Patent Examiner

AU 1626